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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,265	03/22/2006	Graham Stuart Jackson	31288/41195	9057

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,265	JACKSON ET AL.	
	Examiner	Art Unit	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-18,20,21,23 and 28-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-18, 20-21, 23, and 28-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 6-18, 20-21, 23, and 28-38 are presented for reconsideration on the merits.

Response to Amendment

The amendment and extension of time filed November 25, 2008, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-17 and 28-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-17 and 28-38 are vague and indefinite for the recitation of "physical item" because the term is vague and it is not clear what is being defined in the claims.

Claims 29-31 lack antecedent basis for the recitation of "the temperature...." .

Claims 32-33 lack antecedent basis for the recitation of "the final concentration".

Claims 34 lacks antecedent basis for "the time of incubation".

Claims 37-38 are rendered vague and indefinite for the recitation of "removing prion infectivity" and "assessed by bioassay" because these features are vague since they do not clearly define the process steps for carrying them out in the claim of decontamination of prion.

Response to Arguments

Applicant's arguments filed November 25, 2008, have been fully considered but they are not persuasive. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). These are new rejections and what the claim should be interpreted to contain is not relevant because the claim can be interpreted to read on any physical item, which can include anything since limitations of the specification are not read into the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-18, 20-21, 23, and 28-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24

of copending Application No. 11/977844. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference is only in terms of the scope of the claimed subject matter

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

Instantly claimed subject matter is drawn to method, composition and kit for prion decontamination comprising detergent and proteases.

Copending claims are drawn to composition for prion decontamination, method of prion decontamination and kit therefore wherein the composition comprises detergent and proteases.

The difference as noted above is with respect to the scope of the claimed subject matter.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the method, composition and kit all comprising proteases and detergent to decontaminate prions because the copending claims clearly teach that proteases and detergent combinations are well known. Thus, one of skill would have been motivated to provide for the claimed subject matter based upon the copending claimed subject matter. The protease/detergent combination is clearly recognized by the copending claims and the instant claims are hence rendered prima facie obvious over the copending claims.

Response to Arguments

Applicant's arguments filed November 25, 2008, have been fully considered but they are not persuasive. The argument that the copending application was filed after the filing date of the instant application is noted; however, the obviousness double patenting rejection remains pertinent in the instant case because if both applications were to be allowed it is uncertain which one would issue first and hence the obviousness double patenting rejection is sustained. However, the Examiner acknowledges Applicants' request to hold the rejection in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6, 11, 12, 13, 14, 15, 16, 17, 32 and 37-38 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by **newly cited** WO 02/062400 (WO), cited on previously enclosed PTO-1449 Form.

Claims are drawn to a method of prion decontaminaton of a physical item comprising contacting the item with a detergent, and with two different proteases, all performed simultaneously. The detergent is ionic/anion and can be SDS. The item comprises a surface and be a medical instrument containing steel. The process removes prion infectivity which can be assessed by bioassay.

WO teaches a method of prion decontaminaton (see page 1, lines 20-25) of a physical item (see abstract) comprising contacting the item with a detergent, and with two different proteases (see page 9, lines 17-21), all performed simultaneously. The detergent is ionic/anion and can be 2% SDS (page 14, line 21) and (see page 11, line 4). The item comprises a surface (see abstract, line 1) and can be a medical instrument containing steel (page 23, lines 9-10). The process removes prion infectivity which can be assessed by bioassay, note page 18, lines 10-15.

The claims are identical to the teachings of the newly cited WO and are, therefore, considered to be anticipated by the teachings therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-18, 20-21, 23 and 28-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO as cited above, in view of **newly cited** WO 02/053723 and **newly cited** WO 02/083082, WO '892, both cited on previously enclosed PTO-1449 Form.

Claims further drawn to additional steps of autoclaving, incubating and specific SDS concentrations and temperature ranges as well as specific times fold of prion decontamination and specific proteases for use therewith and kit and composition containing the same specific proteases.

WO teaches a method of prion decontaminaton (see page 1, lines 20-25) of a physical item (see abstract) comprising contacting the item with a detergent, and with two different proteases (see page 9, lines 17-21), all performed simultaneously. The detergent is ionic/anion and can be 2% SDS (page 14, line 21) and (see page 11, line 4). The item comprises a surface (see abstract, line 1) and can be a medical instrument containing steel (page 23, lines 9-10). The process removes prion infectivity which can be assessed by bioassay, note page 18, lines 10-15.

WO 02/053723, teaches a method of prion decontaminaton of a physical item comprising contacting the medical item with a detergent and two different enzymes (page 24, lines 14-33) and also with SDS (and page 25 , line 8) and SDS is disclosed to have a final concentration of 2% to 12% (see page 4, lines 23-25). Also incubation

step is disclosed at page 12, line 26. Autoclaving is also disclosed at page 2, line 28. The temperature can be below 100 degrees C, see page 6, line 22.

WO '082 teaches specific enzymes at page 5, line 3 (Proteinase K) and line 6 (papain).

The claims differ from primary WO in that specific SDS concentrations and temperature ranges as well as specific times fold of prion decontamination and specific proteases are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine with the teachings of the cited primary WO reference the teachings of WO 02/053723 and WO '082 to further decontaminate by selecting the steps of incubation and autoclaving, and the specific temperatures and final concentrations of SDS of WO 02/053723, as well as combining the specific proteases disclosed by WO '082 to provide for the method, kit and composition for prion decontamination. Each of the enzymes are well recognized by the cited prior art as is their combination with SDS. Furthermore, the steps of autoclaving and incubation are also well known for these types of processes. Prions are difficult to decontaminate and to select addtional steps well known in the art would have been expected to provide successful results.

The final concentrations of SDS and specific temperatures are well within the purview of an artisan to select, per se and to modify the teachings of WO with these specific conditions would have been obvious and an expected improvement in the art. The composition and kit would have been an obvious modification from the teachings of

WO and WO '082 because each of the protease enzymes are well known; and to combine them with SDS is an obvious modification of the cited prior art. In the absence of unexpected successful results the claims are rendered prima facie obvious over the newly applied cited art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the previously enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/
Deborah K. Ware
Examiner
March 14, 2009

/David M. Naff/
Primary Examiner, Art Unit 1657